RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-10
STANDARDS FOR AMBULATORY SURGICAL TREATMENT CENTERS

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1200-08-10-.01 DEFINITIONS.

(1) Acceptable Plan of Correction. The Licensing Division approves an Ambulatory Surgical Treatment Center's plan to correct deficiencies identified during an on-site survey conducted by the Survey Division or its designated representative. The plan of correction shall be a written document and shall provide, but not limited to, the following information:

(a) How the deficiency will be corrected.

(b) Who will be responsible for correcting the deficiency.

(c) The date the deficiency will be corrected.

(d) How the facility will prevent the same deficiency from re-occurring.

(2) Accredited Record Technician (ART). A person currently accredited as such by the American Medical Records Association.

(3) Adult. An individual who has capacity and is at least 18 years of age.

(4) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

(5) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(6) Ambulatory surgical treatment center (ASTC). Any institution, place or building devoted primarily to the maintenance and operation of a facility for the performance of surgical procedures. Such facilities shall not provide beds or other accommodations for the stay of a patient to exceed twelve (12) hours duration, provided that the length of stay may be extended for an additional twelve (12) hours in the event such stay is deemed necessary by the attending physician, the facility medical director, or the anesthesiologist for observation or recovery, but in no event shall the length of stay exceed twenty-four (24) hours. Individual patients shall be discharged in an ambulatory condition without danger to the continued well-being of the patients or shall be transferred to a hospital. Excluded from this definition are the private physicians' and dentists' office practices. For the purposes of this rule, those

(Rule 1200-08-10-.01, continued)

medical and dental offices, facilities, and other settings at which surgical procedures exclusively are performed are ASTC's and not private office practices.

ASTC's must comply with the following for purposes of these regulations:

(a) surgical procedures performed must be limited to those procedures which are commonly performed on an inpatient basis in hospitals but may safely be performed in an ASTC;

(b) if anesthesia is required for a surgical procedure, it must be local, regional or general anesthesia and routinely be four (4) hours or less in duration;

(c) surgical procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, or are considered emergency or life-threatening in nature may not be performed.

(7) Board. The Tennessee Board for Licensing Health Care Facilities.

(8) Cancer Treatment and Radiation Clinic. A facility in which the only procedures performed are diagnostic and therapeutic radiology, chemotherapy and related services.

(9) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a patient to make health care decisions while having the capacity to do so. A patient shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.

(10) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirators, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(11) Certified Registered Nurse Anesthetist. A registered nurse currently licensed by the Tennessee Board of Nursing who is currently certified as such by the American Association of Nurse Anesthetists.

(12) Clinical Laboratory Improvement Act (CLIA). The federal law requiring that clinical laboratories be approved by the U.S. Department of Health and Human Services, Health Care Financing Administration.

(13) Collaborative Plan. The formal written plan between the mid-level practitioners and licensed physician.

(14) Collaborative Practice. The implementation of the collaborative plan that outlines procedures for consultation and collaboration with other health care professionals, e.g., licensed physicians, mid-level practitioners or nurse midwives.

(15) Commissioner. Commissioner of the Tennessee Department of Health or his or her authorized representative.

(16) Competent. A patient who has capacity.

(Rule 1200-08-10-.01, continued)

~~(17) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:~~

~~(a) the action(s) implemented to prevent the reoccurrence of the unusual incident,~~

~~(b) the time frames for the action(s) to be implemented,~~

~~(c) the person(s) designated to implement and monitor the action(s), and~~

~~(d) the strategies for the measurements of effectiveness to be established.~~

(~~18~~17) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.

(~~19~~18) Department. The Tennessee Department of Health.

(~~20~~19) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.

(~~21~~20) Do Not Resuscitate (DNR) order. An order entered by the patient's treating physician in the patient's medical records which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation.

(~~22~~21) Electronic Signature. The authentication of a health record document or documentation in an electronic form achieved through electronic entry of an exclusively assigned, unique identification code entered by the author of the documentation.

(~~23~~22) Emancipated Minor. Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.

(~~24~~23) Emergency Responder. A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.

(~~25~~24) Gastrointestinal Endoscopy Clinic. A facility in which the only procedures performed are those related to the gastrointestinal tract and other endoscopic procedures. This excludes laparoscopy and limits entry to major body cavities by needle aspiration only.

(~~26~~25) General Anesthesia. An induced state of unconsciousness accompanied by partial or complete loss of protective reflexes inducing the inability to continually maintain an airway independently and respond purposefully to physical stimulation or verbal command, and produced by a pharmacological or non-pharmacological method or a combination thereof.

(~~27~~26) Graduate Registered Nurse Anesthetist. A registered nurse currently licensed in Tennessee who is a graduate of a nurse anesthesia educational program that is accredited by the American Association of Nurse Anesthetist's Council on Accreditation of Nurse Anesthesia Educational Programs and awaiting initial certification examination results, provided that initial certification is accomplished within eighteen (18) months of completion of an accredited nurse anesthesia educational program.

(~~28~~27) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(Rule 1200-08-10-.01, continued)

(~~29~~28) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(~~30~~29) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

(~~31~~30) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~32~~31) Health Care Decision-maker. In the case of a patient who lacks capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed guardian or conservator with health care decision-making authority, the patient's surrogate as determined pursuant to Rule 1200-08-10-.13 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

(~~33~~32) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~34~~33) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

(~~35~~34) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with services of a physician or dentist, to one (1) or more non-related persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.

(~~36~~35) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~37~~36) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~38~~37) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(~~39~~38) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~40~~39) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all applicable rules and regulations.

(~~41~~40) Life Threatening or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~42~~41) Medical emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(Rule 1200-08-10-.01, continued)

(~~43~~42) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(~~44~~43) Medical Staff. An organized body composed of individuals appointed by the ambulatory surgical treatment center governing board. All members of the medical staff shall be licensed to practice in Tennessee, with the exception of interns and residents.

(~~45~~44) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or other medical or surgical treatments to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the patient's representative expresses the goals of the patient.

(~~46~~45) Mid-Level Practitioner. A registered nurse licensed in Tennessee who holds a master's degree in a clinical nursing specialty, national certification through the ANCC or American Academy of Nurse Practitioners and holds a certificate of fitness to prescribe from the Tennessee Board of Nursing.

(~~47~~46) N.F.P.A. National Fire Protection Association.

(~~48~~47) Nurse Midwife. A person currently licensed by the Tennessee Board of Nursing as a registered nurse (R.N.) and qualified to deliver midwifery services or certified by the American College of Nurse-Midwives.

(~~49~~48) Patient. Includes but is not limited to any person who is suffering from an acute or chronic illness or injury or who is crippled, convalescent or infirm, or who is in need of obstetrical, surgical, medical, nursing or supervisory care.

(~~50~~49) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(~~51~~50) PALS. Pediatric Advance Life Support.

(~~52~~51) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~53~~52) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~54~~53) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~55~~54) Physician Assistant. A person who is licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. §63-19-107(2)(A).

(Rule 1200-08-10-.01, continued)

(~~56~~55) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.

(~~57~~56) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.

(~~58~~57) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.

(~~59~~58) Radiological Technologist. A person currently certified as such by the American Society of Radiological Technologists.

(~~60~~59) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~61~~60) Registered Nurse (R.N.). A person currently licensed as such by the Tennessee Board of Nursing.

(~~62~~61) Registered Record Administrator (RRA). A person currently registered as such by the American Medical Records Association.

(~~63~~62) Shall or Must. Compliance is mandatory.

(~~64~~63) State.A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(~~65~~64) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(~~66~~65) Surgical Procedure. A manual or operative method performed by a licensed medical practitioner to treat diseases, injuries, conditions and/or deformities. (As related to pregnancy termination, surgical procedure excludes, but is not limited to, PAP smear or vaginal examinations, ultrasounds, amniocentesis, intramuscular injections.)

(~~67~~66) Surgical Technologist. A person who works under supervision to facilitate the safe and effective conduct of invasive surgical procedures. This individual is usually employed by a hospital, medical office, or surgical center and supervised during the surgical procedure according to institutional policy and procedure to assist in providing a safe operating room environment that maximizes patient safety by performing certain tasks including, but not limited to:

(a) Preparation of the operating room and the sterile field for surgical procedures by preparing sterile supplies, instruments, and equipment using sterile technique;

(b) Preparation of the operating room for surgical procedures by ensuring that surgical equipment is functioning properly and safely; and

(c) Passing instruments, equipment or supplies to a surgeon, sponging or suctioning an operative site, preparing and cutting suture material, holding retractors, transferring but

(Rule 1200-08-10-.01, continued)

not administering fluids or drugs, assisting in counting sponges, needles, supplies, and instruments, and performing other similar tasks as directed during a surgical procedure.

(~~68~~67) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~69~~68) Transfer. The movement of a patient at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

(~~70~~69) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

~~(71) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.~~

(70) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(72) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.~~

~~(73) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, 68-11-216, 68-11-224, 68-11-1802, 68-57-101, 68-57-102 and 68-57-105.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed August 10, 1982; effective September 9, 1982. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Amendment filed March 12, 1993; effective April 26, 1993. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed May 20, 2004; effective August 3, 2004. Amendments filed September 9, 2005; effective November 23, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed February 22, 2010; effective May 23, 2010.*

1200-08-10-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county, or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any ASTC as defined, without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30. The license shall be posted in a conspicuous place in the ASTC.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

(Rule 1200-08-10-.04, continued)

(f) The facility shall develop and implement a system for measuring improvements in adherence to the hand hygiene program, central venous catheter insertion process, and influenza vaccination program.

(22) The ASTC shall ensure a framework for addressing issues related to care at the end of life.

(23) The ASTC shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

(24) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:

(a) Contact information including statewide toll-free number of the division of adult protective services, and the number for the local district attorney's office;

(b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and

(c) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height.

Postings of (a) and (b) shall be on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height.

(25) "No smoking" signs or the international "No Smoking" symbol, consisting of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it, shall be clearly and conspicuously posted at every entrance.

(26) The facility shall develop a concise statement of its charity care policies and shall post such statement in a place accessible to the public.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-17-1803, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, 68-11-268 and 71-6-121.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed September 9, 2005; effective November 23, 2005. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed October 11, 2007; effective December 25, 2007. Amendment filed February 22, 2010; effective May 23, 2010.*

1200-08-10-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(1) Every person admitted for care or treatment to any ASTC shall be under the supervision of a physician licensed to practice in Tennessee. The name, address and telephone number of the physician attending the patient shall be recorded in the patient's medical record.

(2) The above does not preclude the admission of a patient to an ASTC by a dentist or podiatrist licensed to practice in Tennessee with the concurrence of a physician member of the medical staff.

(Rule 1200-08-10-.05, continued)

(3) This does not preclude qualified oral and maxillo-facial surgeons from admitting patients and completing the admission history and physical examination and assessing the medical risk of the procedure on their patients. A physician member of the medical staff is responsible for the management of medical problems.

(4) The facility shall ensure that no person on the grounds of race, color, national origin, or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the facility. The facility shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

(5) For purposes of this chapter, the requirements for signature or countersignature by a physician, dentist, podiatrist or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established ASTC protocol or rules.

(6) Each ASTC must have a written transfer agreement with a local hospital.

(7) The ASTC shall develop a patient referral system both for referrals within the facility and other health care providers.

(8) The ASTC shall have available a plan for emergency transportation to a licensed local hospital.

(9) The facility must ensure continuity of care and provide an effective discharge planning process that applies to all patients. The facility's discharge planning process, including discharge policies and procedures, must be specified in writing and must:

(a) Be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel;

(b) Begin upon admission;

(c) Be provided when identified as a need by the patient, a person acting on the patient's behalf, or by the physician; and

(d) Include the likelihood of a patient's capacity for self-care or the possibility of the patient returning to his or her pre-ambulatory surgical treatment center environment.

(10) A discharge plan is required on every patient, even if the discharge is to home.

(11) The facility must arrange for the initial implementation of the patient's discharge plan and must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(12) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-operative care.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

(Rule 1200-08-10-.05, continued)

1200-08-10-.06 BASIC SERVICES.

(1) Surgical Services.

(a) Facilities restricted in services they provide, e.g. those that restrict services to radiation therapy or use of local anesthetics only, may be exempted from all or part of the requirements of this rule pertaining to laboratory services, food and dietetic services, surgical services, and anesthesia services.

(b) If the facility provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(c) A hospital may choose to separately license a portion of the facility as an Ambulatory Surgical Treatment Center; the licensure fee for such is not required.

(d) The organization of the surgical services must be appropriate to the scope of the services offered.

(e) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

~~(f) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.~~

(f) An ASTC may use scrub nurses in its operating rooms. For the purposes of this rule, a "scrub nurse" is defined as a registered nurse or either a licensed practical nurse (L.P.N.) or a surgical technologist (operating room technician) supervised by a registered nurse who works directly with a surgeon within the sterile field, passing instruments, sponges, and other items needed during the procedure and who scrubs his or her hands and arms with special disinfecting soap and wears surgical gowns, caps, eyewear, and gloves, when appropriate.

(g) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

(h) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(i) Surgical services must be consistent with needs and resources. Policies covering surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(j) Surgical technologists must:

1. Hold current national certification established by the Liaison Council on Certification for the Surgical Technologist (LCC-ST); or

2. Have completed a program for surgical technology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or

(Rule 1200-08-10-.06, continued)

3. Have completed an appropriate training program for surgical technologists in the armed forces or at a CAAHEP accredited hospital or CAAHEP accredited ambulatory surgical treatment center; or

4. Successfully complete the surgical technologists LCC-ST certifying exam; or

5. Provide sufficient evidence that, prior to May 21, 2007, the person was at any time employed as a surgical technologist for not less than eighteen (18) months in the three (3) years preceding May 21, 2007 in a hospital, medical office, surgery center, or an accredited school of surgical technology; or has begun the appropriate training to be a surgical technologist prior to May 21, 2007, provided that such training is completed within three (3) years of May 21, 2007.

(k) An ASTC can petition the director of health care facilities of the department for a waiver from the provisions of 1200-08-10-.06(1)(j) if they are unable to employ a sufficient number of surgical technologists who meet the requirements. The facility shall demonstrate to the director that a diligent and thorough effort has been made to employ surgical technologist who meet the requirements. The director shall refuse to grant a waiver upon finding that a diligent and thorough effort has not been made. A waiver shall exempt a facility from meeting the requirements for not more than nine (9) months. Additional waivers may be granted, but all exemptions greater than twelve (12) months shall be approved by the Board for Licensing Health Care Facilities.

(l) Surgical technologists shall demonstrate continued competence in order to perform their professional duties in surgical technology. The employer shall maintain evidence of the continued competence of such individuals. Continued competence activities may include but are not limited to continuing education, in-service training, or certification renewal.

(m) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If the history has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(n) Properly executed informed consent, advance directive, and organ donation forms must be in the patient's chart before surgery, except in emergencies.

(o) Adequate equipment and supplies must be available to the operating room suites and to the post-operative care area;

1. Call-in system (OR)

2. Cardiac monitor

3. Pulse Oximeter

4. Resuscitator

5. Defibrillator

6. Aspirator

7. Tracheotomy set

(Rule 1200-08-10-.06, continued)

(p) A crash cart must be available and include at a minimum the following medication and supplies:

1. adrenalin (epinephrine) 1: 10,000 dilution; 10 ml
2. adrenalin (epinephrine) 1:1000 dilution; 1 ml
3. atropine 0.1 mg/ml
4. benadryl (diphenhydramine)
5. calcium chloride 10%; 10ml amp
6. dextrose. 50%
7. dilantin (phentoin)
8. dopamine
9. heparin
10. inderal (proprandolol)
11. isuprel
12. lanoxin (digoxin)
13. lasix (furosemide)
14 xylocaine (lidocaine)
15. magnesium sulfate 50%
16. narcan (naloxone)
17. pronestyl (procainaimide)
18. sodium bicarbonate 50 mEq/50ml
19. solu-medrol (methylprednisolone)
20. verapamil hydrochloride
21. mazicon
22. Suction devices, endotracheal tubes, laryngoscopes, etc.,
23. Positive pressure ventilation device (e.g., Ambu) plus oxygen supply.
24. Double tourniquet for the Bier block procedure.
25. Emergency intubation equipment.
26. IV solution and IV equipment.

(Rule 1200-08-10-.06, continued)

(q) At least one registered nurse shall be in the recovery area during the patient's recovery period.

(r) The operating room register must be complete and up-to-date.

(s) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

(t) The ASTC shall provide one or more surgical suites which shall be constructed, equipped, and maintained to assure the safety of patients and personnel.

(u) Surgical suites are required to meet the same standards as hospital operating rooms, including those using general anesthesia.

(v) The ASTC shall have separate areas for waiting rooms, recovery rooms, treatment and/or examining rooms.

(2) Anesthesiology Services. Anesthesia shall be administered by:

(a) A qualified anesthesiologist;

(b) A doctor of medicine or osteopathy (other than an anesthesiologist);

(c) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(d) A certified registered nurse anesthetist (CRNA); or

(e) A graduate registered nurse anesthetist under the supervision of an anesthesiologist who is immediately available if needed.

(f) After the completion of anesthesia, patients shall be constantly attended by competent personnel until responsive and able to summon aid. Each center shall maintain a log of the inspections made prior to each day's use of the anesthesia equipment. A record of all service and maintenance performed on all anesthesia machines, vaporizers and ventilators shall also be on file.

(g) When general anesthesia and/or succinylcholine are administered, the facility shall maintain thirty-six (36) ampules of dantrolene for injection on site. If dantrolene is administered, appropriate monitoring must be provided post operatively.

(h) Written policies and procedures relative to the administration of anesthesia shall be developed and approved by the Medical Staff and governing body.

(i) Any patient receiving conscious sedation shall receive:

1. continuous EKG monitoring;

2. continuous oxygen saturations;

3. serial BP monitoring at intervals no less than every 5 minutes; and

4. supplemental oxygen therapy and immediately available:

(i) ambubag;

(Rule 1200-08-10-.06, continued)

(ii) suction;

(iii) endotracheal tube; and

(iv) crash cart.

(3) Medical Staff.

(a) The ASTC shall have a medical staff organized under written by-laws that are approved by the governing body. The medical staff of the ASTC shall define a mechanism to:

1. Assure that an optimal level of professional performance is maintained;

2. Appoint independent practitioners through a defined credentialing process;

3. Apply credentialing criteria uniformly;

4. Utilize the current license, relevant training and experience, current competence and the ability to perform requested privileges in the credentialing process; and

5. Provide for participation in required committees of the facility to ensure that quality medical care is provided to the patients.

(b) Each licensed independent practitioner shall provide care under the auspices of the facility in accordance with approved privileges.

(c) Clinical privileges shall be granted based on the practitioners' qualifications and the services provided by the facility, and shall be reviewed and/or revised at least every two (2) years.

(4) Nursing Service. A licensed registered nurse (R.N.) shall be on duty at all times. Additional appropriately trained staff shall be provided as needed to ensure that the medical needs of the patients are fully met.

(a) The ASTC shall be organized under written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care and nursing services.

(b) A qualified registered nurse designated by the administrator shall be responsible for coordinating and supervising all nursing services.

(c) There shall be a sufficient staffing pattern of registered nurses to provide quality nursing care to each surgical patient from admission through discharge. Additional staff shall be on duty and available to assist the professional staff to adequately handle routine and emergency patient needs.

(d) The ASTC shall establish written procedures for emergency services which will ensure that professional staff members who have been trained in emergency resuscitation procedures shall be on duty at all times when there is a patient in the ASTC and until the patient has been discharged.

(e) Nursing care policies and procedures shall be consistent with professionally recognized standards of nursing practice and shall be in accordance with the Nurse Practice Act of

(Rule 1200-08-10-.06, continued)

the State of Tennessee and the Association of Operating Room Nurses Standards of Practice.

(f) Staff development and training shall be provided to the nursing staff and other ancillary staff in order to maintain and improve knowledge and skills. The educational/training program shall be planned, documented and conducted on a continuing basis. There shall be at least appropriate training on equipment, safety concerns, infection control and emergency care on an annual basis.

(5) Pharmaceutical Services. The ASTC must provide drugs and biologicals in a safe and effective manner in accordance with accepted standards of practice. Such drugs and biologicals must be stored in a separate room or cabinet which shall be kept locked at all times.

(6) Ancillary Services. All ancillary or supportive health or medical services, including but not limited to, radiological, pharmaceutical, or medical laboratory services shall be provided in accordance with all applicable state and federal laws and regulations.

(7) Radiological Services. The ASTC shall provide within the facility, or through arrangement, diagnostic radiological services commensurate with the needs of the ambulatory surgical treatment center.

(a) If radiological services are provided by facility staff, the services shall be maintained free of hazards for patients and personnel.

(b) New installations of radiological equipment, and subsequent inspections for the identification of radiation hazards shall be made as specified in state and federal requirements.

(c) Personnel monitoring shall be maintained for each individual working in the area of radiation. Readings shall be on at least a monthly basis and reports kept on file and available for review.

1. Personnel - The ASTC shall have a radiologist either full-time or part-time on a consulting basis, both to supervise the service and to discharge professional radiological services.

2. The use of all radiological apparatus shall be limited to personnel designated as qualified by the radiologist; and use of fluoroscopes shall be limited to physicians.

(d) If provided under arrangement with an outside provider, the radiological services must be directed by a qualified radiologist and meet state and federal requirements.

(8) Laboratory Services.

(a) The ASTC shall provide on the premises or by written agreement with a laboratory licensed under T.C.A. 68-29-105, a clinical laboratory to provide those services commensurate with the needs and services of the ASTC.

(b) Any patient terminating pregnancy in an ASTC shall have an Rh type, documented prior to the procedure, performed on her blood. In addition, she shall be given the opportunity to receive Rh immune globulin after an appropriate crossmatch procedure is performed within a licensed laboratory.

(Rule 1200-08-10-.06, continued)

(9) Food and Dietetic Services. If a patient will be in the facility for more than four (4) hours post-op, an appropriate diet shall be provided.

(10) Environmental Services.

(a) The facility shall provide a safe, accessible, effective and efficient environment of care consistent with its mission, service, law and regulation.

(b) The facility shall develop policies and procedures that address:

1. Safety;

2. Security;

3. Control of hazardous materials and waste;

4. Emergency preparedness;

5. Life safety;

6. Medical equipment; and,

7. Utility systems.

(c) Staff shall have been oriented to and educated about the environment of care and possess knowledge and skills to perform responsibilities under the environment of care policies and procedures.

(d) Utility systems, medical equipment, life safety elements, and safety elements of the environment of care shall be maintained, tested and inspected.

(e) Safety issues shall be addressed and resolved.

(f) Appropriate staff shall participate in implementing safety recommendations and monitoring their effectiveness.

(g) The building and grounds shall be suitable to services provided and patients served.

(11) Medical Records.

(a) The ASTC shall comply with the Medical Records Act of 1974, T.C.A. § 68-11-301, et seq.

(b) A medical record shall be maintained for each person receiving medical care provided by the ASTC and shall include:

1. Patient identification;

2. Name of nearest relative or other responsible agent;

3. Identification of primary source of medical care;

4. Dates and times of visits;

5. Signed informed consent;

(Rule 1200-08-10-.06, continued)

6. Pertinent medical history;

7. Diagnosis;

8. Physician examination report;

9. Anesthesia records of pertinent preoperative and postoperative reports including preanesthesia evaluation, type of anesthesia, technique and dosage used;

10. Operative report;

11. Discharge summary, including instructions for self care and instructions for obtaining postoperative emergency care;

12. Reports of all laboratory and diagnostic procedures along with tests performed and the results authenticated by the appropriate personnel; and,

13. X-ray reports.

(c) Medical records shall be current and confidential. Medical records and copies thereof shall be made available when requested by an authorized representative of the board or the department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68, 68-11-209, 68-11-216, 68-57-101, 68-57-102, ~~and~~ 68-57-104, and 68-57-105.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September 10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed February 22, 2010; effective May 23, 2010.*

1200-08-10-.07 RESERVED.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 4, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

1200-08-10-.08 BUILDING STANDARDS.

(1) The ambulatory surgical treatment center must be constructed, arranged, and maintained to ensure the safety of the patient.

(2) The condition of the physical plant and the overall ambulatory surgical treatment center environment must be developed and maintained in such a manner that the safety and well-being of residents are assured.

(3) No ambulatory surgical treatment center shall hereafter be constructed, nor shall major alterations be made to existing ambulatory surgical treatment centers, or change in an ambulatory surgical treatment center type be made without the prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new ambulatory surgical treatment center is licensed or before any alteration or expansion of a licensed ambulatory surgical treatment center can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications

(Rule 1200-08-10-.10, continued)

the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (non-hazardous) solid waste under current rules of the Department of Environment and Conservation.

(b) The facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. § 69-3-101 et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.

(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the facility must ensure that it has all necessary State and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable Federal and State requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this subparagraph. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.

(11) All garbage, trash and other non-infectious wastes shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, be constructed of easily cleanable material and be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed July 3, 1984; effective August 1, 1984. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed September 9, 2005; effective November 23, 2005.*

1200-08-10-.11 RECORDS AND REPORTS.

(1) The Joint Annual Report of Ambulatory Surgical Treatment Centers shall be filed with the department. The forms are furnished and mailed to each ASTC by the department each year and the forms must be completed and returned to the department as required.

(Rule 1200-08-10-.11, continued)

(2) The facility shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(3) The ASTC shall report to the department each case of communicable disease detected in the center. Repeated failure to report communicable diseases shall be cause for revocation of an ASTC's license.

~~(4) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.~~

~~(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:~~

~~1. medication errors;~~

~~2. aspiration in a non-intubated patient related to conscious/moderate sedation;~~

~~3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;~~

~~4. volume overload leading to pulmonary edema;~~

~~5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;~~

~~6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;~~

~~7. burns of a second or third degree;~~

~~8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;~~

~~9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:~~

~~(i) procedure related injury requiring repair or removal of an organ;~~

~~(ii) hemorrhage;~~

~~(iii) displacement, migration or breakage of an implant, device, graft or drain;~~

~~(iv) post operative wound infection following clean or clean/contaminated case;~~

(Rule 1200-08-10-.11, continued)

~~(v) any unexpected operation or reoperation related to the primary procedure;~~

~~(vi) hysterectomy in a pregnant woman;~~

~~(vii) ruptured uterus;~~

~~(viii) circumcision;~~

~~(ix) incorrect procedure or incorrect treatment that is invasive;~~

~~(x) wrong patient/wrong site surgical procedure;~~

~~(xi) unintentionally retained foreign body;~~

~~(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;~~

~~(xiii) criminal acts;~~

~~(xiv) suicide or attempted suicide;~~

~~(xv) elopement from the facility;~~

~~(xvi) infant abduction, or infant discharged to the wrong family;~~

~~(xvii) adult abduction;~~

~~(xviii) rape;~~

~~(xix) patient altercation;~~

~~(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;~~

~~(xxi) restraint related incidents; or~~

~~(xxii) poisoning occurring within the facility.~~

~~(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:~~

~~1. strike by the staff at the facility;~~

~~2. external disaster impacting the facility;~~

~~3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and~~

~~4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.~~

(Rule 1200-08-10-.11, continued)

~~(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.~~

~~(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.~~

~~(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.~~

~~(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.~~

~~(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.~~

~~(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.~~

~~(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law~~

(Rule 1200-08-10-.11, continued)

~~with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.~~

~~(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.~~

~~(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(4) The ASTC shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(5) The ASTC shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ASTC or to the health and safety of its patients and personnel; and

(d) Fires at the ASTC that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

(~~5~~6) The ASTC shall retain legible copies of the following records and reports which shall be retained in the facility, shall be maintained in a single file, and shall be made available for inspection during normal business hours to any patient who requests to view them for thirty-six (36) months following their issuance:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any;

(Rule 1200-08-10-.11, continued)

(f) Federal Health Care Financing Administration surveys and inspections, if any;

(g) Orders of the Commissioner or Board, if any;

(h) Comptroller of the Treasury's audit reports and finding, if any; and,

(i) Maintenance records of all safety equipment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-1-1004, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September 10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-08-10-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. § 71-6-101 et seq;

(c) To refuse treatment. The patient must be informed of the consequences of that decision, the refusal and its reason must be reported to the physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in his or her medical record;

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The ambulatory surgical treatment center must have policies to govern access and duplication of the patient's record;

(f) To have appropriate assessment and management of pain; and

(g) To be involved in the decision making of all aspects of their care.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed September 9, 2005; effective November 23, 2005.*

1200-08-10-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each ambulatory surgical treatment center shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(Rule 1200-08-10-.13, continued)

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

(Rule 1200-08-10-.13, continued)

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-10-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-10-.13(16)(c) thru 1200-08-10-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except

(Rule 1200-08-10-.13, continued)

that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-10-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-10-.13(20) thru 1200-08-10-.13(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(Rule 1200-08-10-.13, continued)

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-10-.13(20) thru 1200-08-10-.13(22) shall:

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(Rule 1200-08-10-.13, continued)

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(Rule 1200-08-10-.13, continued)

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed June 22, 1992; effective August 6, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed September 9, 2005; effective November 23, 2005. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-10-.14 DISASTER PREPAREDNESS.

RULES
OF
TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-11
STANDARDS FOR HOMES FOR THE AGED

TABLE OF CONTENTS

1200-08-11-.01 DEFINITIONS.

(1) Activities of Daily Living (ADL's). Those personal functional activities which indicate an individual's independence in eating, dressing, personal hygiene, bathing, toileting, and moving from one place to another.

(2) Adult. An individual who has capacity and is at least 18 years of age.

(3) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

(4) Aged. A person who is fifty-five (55) years of age or older.

(5) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(6) Ambulatory resident. A resident who is physically and mentally capable under emergency conditions of finding a way to safety without physical assistance from another person. An ambulatory resident may use a cane, wheelchair or other supportive device and may require verbal prompting.

(7) Board. The Tennessee Board for Licensing Health Care Facilities.

(8) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a resident to make health care decisions while having the capacity to do so. A resident shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a resident shall have the burden of proving lack of capacity.

(9) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to restore or support cardiopulmonary function in a resident, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(Rule 1200-08-11-.01, continued)

(10) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

~~(11) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:~~

~~(a) the action(s) implemented to prevent the reoccurrence of the unusual event,~~

~~(b) the time frames for the action(s) to be implemented,~~

~~(c) the person(s) designated to implement and monitor the action(s), and~~

~~(d) the strategies for the measurements of effectiveness to be established.~~

(~~12~~11) Department. The Tennessee Department of Health.

(~~13~~12) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.

(~~14~~13) Emancipated Minor. Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.

(~~15~~14) Emergency. Any situation or condition which presents an imminent danger of death or serious physical or mental harm to residents.

(~~16~~15) Emergency responder. A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.

(~~17~~16) Evacuation Capability. The ability to either evacuate the building or move to a point of safety.

(~~18~~17) Guardian. A judicially appointed guardian of conservator having authority to make a health care decision

(~~19~~18) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state, or federal regulations.

(~~20~~19) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. 32-11-103(5)

(~~21~~20) Health care decision. Consent, refusal or consent or withdrawal of consent to health care.

(~~22~~21) Health Care Decision-maker. In the case of a resident who lacks capacity, the resident's health care decision-maker is one of the following: the resident's health care agent as specified in an advance directive, the resident's court-appointed guardian or conservator with healthcare decision-making authority, the resident's surrogate as determined pursuant to Rule 1200-08-11-.12 or T.C.A. 33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

(~~23~~22) Health Care Institution. A health care institution as defined in T.C.A. 68-11-1602.

(Rule 1200-08-11-.01, continued)

(~~24~~23) Health Care Provider A person who si licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

(~~25~~24) Holding Out to the Public. Advertising or soliciting the public through the use of personal, telephone, mail or other forms of communication to provide information about services provided by the facility.

(~~26~~25) Home for the Aged. A home represented and held out to the general public as a home which accepts primarily aged persons for relatively permanent, domiciliary care with primarily being defined as 51% or more of the population of the home for the aged. It provides room, board and personal services to four (4) or more nonrelated persons. The term home includes any building or part thereof which provides services as defined in these rules.

(~~27~~26) Home for the Aged Resident. A person who is ambulatory and who requires permanent, domiciliary care but who will be transferred to a licensed hospital, licensed nursing home or licensed assisted care living facility when health care services are needed which must be provided in such other facilities.

(~~28~~27) Incompetent. A resident who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~29~~28) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~30~~29) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(~~31~~30) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~32~~31) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~33~~32) Medically Inappropriate Treatment Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the resident or other medical or surgical treatments to achieve the expressed goals of the informed resident. In the case of the incompetent resident, the resident's representative expresses the goals of the resident

(~~34~~33) N.F.P.A. The National Fire Protection Association.

(~~35~~34) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(~~36~~35) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency or instrumentality, or any other legal or commercial entity.

(Rule 1200-08-11-.01, continued)

(~~37~~36) Personal Services. Those services that are rendered to residents who need supervision or assistance in activities of daily living. Personal services must include protective care of the resident, responsibility for the safety of the resident when in the facility, daily awareness of the resident's whereabouts and the ability and readiness to intervene if crises arise. Personal services do not include nursing or medical care.

(~~38~~37) Personally Informing. A communication by any effective means from the resident directly to a health care provider.

(~~39~~38) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2

(~~40~~39) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency services personnel providers, or entities acting within the usual course of their professions, and other emergency responders.

(~~41~~40) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the resident's health care needs. Such availability shall include, but not limited to, availability by telephone.

(~~42~~41) Responsible Attendant. The person designated by the licensee who remains awake to provide personal services to the residents. In the absence of the licensee, the responsible attendant is responsible for ensuring the home complies with all rules and regulations.

(~~43~~42) Secured Unit. A facility or distinct part of a facility where the residents are intentionally denied egress by any means.

(~~44~~43) Shall or Must. Compliance is mandatory.

(~~45~~44) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(~~46~~45) Supervising Heath Care Provider. The designated physician or, if there is no designated physician ot the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(~~47~~46) Surrogate. An individual, other that a resident's agent or guardian, authorized to make a health care decision for the resident.

(~~48~~47) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the resident.

~~(49) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.~~

(48) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(50) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.~~

(Rule 1200-08-11-.01, continued)

~~(51) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-216, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed June 21, 1979; effective August 6, 1979. Amendment filed August 16, 1988; effective September 30, 1988. Amendment filed January 30, 1992; effective March 15, 1992. Amendment filed December 7, 1993; effective February 20, 1994. Repeal and new rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003.Amendment filed September 8, 2006; effective November 22, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed February 23, 2007; effective May 9, 2007*

1200-08-11-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate, or maintain in the State of Tennessee any home for the aged without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the facility.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

(b) Each applicant for a license shall pay an annual license fee based on the number of beds as follows:

1.	Less than 6 beds	$ 300.00
2.	6 to 24 beds, inclusive	$ 800.00
3.	25 to 49 beds, inclusive	$ 1,000.00
4.	50 to 74 beds, inclusive	$ 1,200.00
5.	75 to 99 beds, inclusive	$ 1,400.00
6.	100 to 124 beds, inclusive	$ 1,600.00
7.	125 to 149 beds, inclusive	$ 1,800.00
8.	150 to 174 beds, inclusive	$ 2,000.00
9.	175 to 199 beds, inclusive	$ 2,200.00

For homes for the aged of two hundred (200) beds or more the fee shall be two thousand four hundred dollars ($2,400.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Residents shall not be admitted to the home until a license has been issued.

(Rule 1200-08-11-.09, continued)

waste that has been rendered to carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (non-hazardous) solid waste under current rules of the Department of Environment and Conservation.

(b) A facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. §§ 69-3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.

(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county, and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the facility must ensure that it has all necessary State and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this rule.

(11) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily-cleanable material, and shall be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed June 21, 1979; effective August 6, 1979. Repeal and new rule filed July 27, 2000; effective October 10, 2000.*

1200-08-11-.10 RECORDS AND REPORTS.

(1) An individual resident file shall be maintained for each resident in the home. Personal information shall be confidential and shall not be disclosed, except to the resident, the department and others with written authorization from the resident. These files shall be retained for one (1) year after the resident is transferred or discharged. The resident file shall include:

(a) Name, Social Security Number, veteran status and number, marital status, age, sex, previous address and any health insurance provider and number, including Medicare and Medicaid numbers;

(b) Name, address and telephone number of next of kin, legal guardian and any other person identified by the resident to contact on his/her behalf;

(c) Name, address and telephone number of any person or agency providing additional services to the resident;

(d) Date of admission, transfer, discharge and any new forwarding address;

(e) Name and address of the resident's preferred physician, hospital, pharmacist, assisted care living facility and nursing home, and any other instructions from the resident to be followed in case of emergency;

(f) Record of all monies and other valuables entrusted to the home for safekeeping, with appropriate updates;

(g) Health information including all current prescriptions, major changes in resident's habits or health status, results of physician's visits, and any health care instructions; and

(h) A copy of the admission agreement signed and dated by the resident.

~~(2) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.~~

~~(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:~~

~~1. medication errors;~~

~~2. aspiration in a non-intubated patient related to conscious/moderate sedation;~~

~~3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;~~

~~4. volume overload leading to pulmonary edema;~~

~~5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;~~

~~6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;~~

~~7. burns of a second or third degree;~~

~~8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;~~

~~9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:~~

~~(i) procedure related injury requiring repair or removal of an organ;~~

~~(ii) hemorrhage;~~

(Rule 1200-08-11-.10, continued)

(iii) displacement, migration or breakage of an implant, device, graft or drain;

(iv) post operative wound infection following clean or clean/contaminated case;

(v) any unexpected operation or reoperation related to the primary procedure;

(vi) hysterectomy in a pregnant woman;

(vii) ruptured uterus;

(viii) circumcision;

(ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

(Rule 1200-08-11-.10, continued)

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(Rule 1200-08-11-.10, continued)

~~(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.~~

~~(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.~~

~~(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(2) The RHA shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(3) The RHA shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ASTC or to the health and safety of its patients and personnel; and

(d) Fires at the ASTC that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires

(34) Legible copies of the following records and reports shall be retained in the facility, shall be maintained in a single file, and shall be made available for inspection during normal business hours for thirty-six (36) months following their issuance. Each resident and each person assuming any financial responsibility for a resident must be fully informed, before admission, of their existence in the home and given the opportunity to inspect the file before entering into any monetary agreement with the facility.

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Department licensure and fire safety inspections and surveys;

(Rule 1200-08-11-.10, continued)

(d) Orders of the Commissioner or Board, if any; and

(e) Maintenance records of all safety equipment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213.* ***Administrative History:*** *Original rule filed June 21, 1979; effective August 6, 1979. Amendment filed February 26, 1985; effective March 28, 1985. Amendment filed August 16, 1988; effective September 30, 1988. Repeal and new rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed December 23, 2009; effective March 23, 2010.*

1200-08-11-.11 RESIDENT RIGHTS. Each resident has at least the following rights:

(1) To privacy in treatment and personal care;

(2) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department within five (5) working days. The Tennessee Department of Human Services, Adult Protective Services shall be notified immediately as required in T.C.A. § 71-6-103;

(3) To refuse treatment. The resident must be informed of the consequences of that decision, and the refusal and its reason must be reported to the physician and documented in the resident's record;

(4) To have his or her file kept confidential and private. Written consent by the resident must be obtained prior to release of information except to persons authorized by law;

(5) To be fully informed of the Resident's Rights, of any policies and procedures governing resident conduct, any services available in the home and the schedule of all fees for all services ;

(6) To participate in drawing up the terms of the admission agreement, including providing for the resident's preferences for physician care, hospitalization, assisted living facility care, nursing home care, acquisition of medication, emergency plans and funeral arrangements;

(7) To be given thirty (30) days written notice prior to transfer or discharge, except when ordered by any physician because a higher level of care is required;

(8) To voice grievances and recommend changes in policies and services of the home with freedom from restraint, interference, coercion, discrimination or reprisal. The resident shall be informed of procedures for registering complaints confidentially and to voice grievances;

(9) To manage his or her personal financial affairs, including the right to keep and spend his or her own money. If the resident requests assistance from the home in managing his or her personal financial affairs, the request must be in writing and may be terminated by the resident at any time. The home must separate such monies from the home's operating funds and all other deposits or expenditures, submit a written accounting to the resident at least quarterly, and immediately return the balance upon transfer or discharge. A current copy of this report shall be maintained in the resident's file maintained by the licensee;

(10) To be treated with consideration, respect and full recognition of his or her dignity and individuality;

(11) To be accorded privacy for sleeping and for storage space for personal belongings;

(Rule 1200-08-11-.11, continued)

(12) To have free access to day rooms, dining and other group living or common areas at reasonable hours and to come and go from the home, unless such access infringes upon the rights of other residents or unless the resident is admitted to the secured unit;

(13) To wear his or her own clothes, to keep and use his or her own toilet articles and personal possessions;

(14) To send and receive unopened mail;

(15) To associate and communicate privately with persons of his or her choice, including receiving visitors at reasonable hours;

(16) To participate or to refuse to participate in community activities, including cultural, educational, religious, community service, vocational and recreational activities;

(17) To not be required to perform services for the home. The resident and licensee may mutually agree, in writing, for the resident to perform certain activities or services as part of the fee for his or her stay; and,

(18) To execute, modify, or rescind a Living Will.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed June 21, 1997; effective August 6, 1979. Amendment filed August 16, 1988; effective September 30, 1988. Repeal and new rule filed July 27, 2000; effective October 10, 2000.*

1200-08-11-.12 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each home for the aged shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a resident who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual residents. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the resident could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the resident could have made while having capacity.

(3) The advance directive shall be in writing, signed by the resident, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the resident by blood, marriage, or adoption and would not be entitled to any portion of the estate of the resident upon the death of the resident. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the resident lacks capacity, and ceases to be effective upon a determination that the resident has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a resident lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the resident's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the resident's best interest. In determining the resident's best interest, the agent shall consider the resident's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the resident's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(Rule 1200-08-11-.12, continued)

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A resident having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A resident having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a resident who is an adult or emancipated minor if and only if:

1. the resident has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a resident who lacks capacity, the resident's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the resident is receiving health care.

(d) The resident's surrogate shall be an adult who has exhibited special care and concern for the resident, who is familiar with the resident's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, be given in order of descending preference for service as a surrogate to:

1. the resident's spouse, unless legally separated;

2. the resident's adult child;

3. the resident's parent;

4. the resident's adult sibling;

(Rule 1200-08-11-.12, continued)

5. any other adult relative of the resident; or

6. any other adult who satisfies the requirements of 1200-08-11-.12(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the resident shall be eligible to serve as the resident's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the resident or in accordance with the resident's best interests;

2. The proposed surrogate's regular contact with the resident prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the resident during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the resident lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-11-.12(16)(c) thru 1200-08-11-.12(16)(g) is reasonably available, the designated physician may make health care decisions for the resident after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the resident's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the resident's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the resident's best interest. In determining the resident's best interest, the surrogate shall consider the resident's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the resident may make all health care decisions for the resident that the resident could make on the resident's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a resident upon a decision of the surrogate only when the designated physician and a second

(Rule 1200-08-11-.12, continued)

independent physician certify in the resident's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the resident is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-11-.12(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the resident's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the resident by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the resident's individual instructions and may not revoke the resident's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a resident lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the resident's current clinical record and communicate the determination to the resident, if possible, and to any person then authorized to make health care decisions for the resident.

(19) Except as provided in 1200-08-11-.12(20) thru 1200-08-11-.12(22), a health care provider or institution providing care to a resident shall:

(a) comply with an individual instruction of the resident and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the resident; and

(b) comply with a health care decision for the resident made by a person then authorized to make health care decisions for the resident to the same extent as if the decision had been made by the resident while having capacity.

(Rule 1200-08-11-.12, continued)

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the resident or to a person then authorized to make health care decisions for the resident.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-11-.12(20) thru 1200-08-11-.12(22) shall:

(a) promptly so inform the resident, if possible, and any person then authorized to make health care decisions for the resident;

(b) provide continuing care to the resident until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the resident or person then authorized to make health care decisions for the resident refuses assistance, immediately make all reasonable efforts to assist in the transfer of the resident to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a resident has the same rights as the resident to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a resident, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(Rule 1200-08-11-.12, continued)

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a resident in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the resident is an adult who is capable of making an informed decision, the resident's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the resident is a minor or is otherwise incapable of making an informed decision, the expression of the desire that

(Rule 1200-08-11-.12, continued)

the resident be resuscitated by the person authorized to consent on the resident's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the resident in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the resident's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a resident in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed June 22, 1992; effective August 6, 1992. Repeal and new rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed September 8, 2006; effective November 22, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-11-.13 DISASTER PREPAREDNESS.

(1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans for the protection of all persons in the event of fire and other emergencies for evacuation to areas of refuge and/or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans

RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-15
STANDARDS FOR RESIDENTIAL HOSPICES

TABLE OF CONTENTS

1200-08-15-.01 DEFINITIONS.

(1) Administrator. An individual appointed by a governing body who is responsible for the day to day management of the hospice program.

(2) Adult. An individual who has capacity and is at least 18 years of age.

(3) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

(4) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(5) Bereavement Counseling. Counseling services provided to the patient's or resident's family both prior to and after the patient's or resident's death.

(6) Bereavement Counselor. An individual who has at least a bachelor's degree in social work, counseling, psychology, pastoral care, or specialized training or experience in bereavement theory and counseling.

(7) Board. The Tennessee Board for Licensing Health Care Facilities.

(8) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a patient or resident to make health care decisions while having the capacity to do so. A patient or resident shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a patient or resident shall have the burden of proving lack of capacity.

(9) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient or resident, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient or resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(Rule 1200-08-15-.01, continued)

(10) Certified Master Social Worker. A person currently certified as such by the Tennessee Board of Social Worker Certification and Licensure.

(11) Clinical Note. A written and dated notation containing a patient or resident assessment, responses to medications, treatments and services, and/or any changes in condition signed by a health team member who made contact with the patient or resident.

(12) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(13) Competent. A patient or resident who has capacity.

(14) Core Services. Services consisting of nursing, medical social services, physician services and counseling services.

~~(15) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:~~

~~(a) the action(s) implemented to prevent the reoccurrence of the unusual event,~~

~~(b) the time frames for the action(s) to be implemented,~~

~~(c) the person(s) designated to implement and monitor the action(s), and~~

~~(d) the strategies for the measurements of effectiveness to be established.~~

(~~16~~15) Department. The Tennessee Department of Health.

(~~17~~16) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.

(~~18~~17) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners. Persons exempt from licensure shall be registered with the American Diabetics Association pursuant to T.C.A. §63-25-204.

(~~19~~18) Do Not Resuscitate (DNR) Order. An order entered by the patient's or resident's treating physician in the patient's medical records which states that in the event the patient or resident suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(~~20~~19) Emancipated Minor. Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.

(~~21~~20) Emergency Responder. A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.

(~~22~~21) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~23~~22) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state, or federal regulations.

(Rule 1200-08-15-.01, continued)

(~~24~~23) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

(~~25~~24) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~26~~25) Health Care Decision-maker. In the case of a patient or resident who lacks capacity, the patient's or resident's health care decision-maker is one of the following: the patient's or resident's health care agent as specified in an advance directive, the patient's or resident's court-appointed guardian or conservator with health care decision-making authority, the patient's or resident's surrogate as determined pursuant to Rule 1200-08-15-.13 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

(~~27~~26) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~28~~27) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

(~~29~~28) HIV Resident. An individual who is in need of domiciliary care and who has been diagnosed and certified in writing by a licensed physician as being HIV (human immunodeficiency virus) positive.

(~~30~~29) Home Care Organization. As defined by T.C.A. § 68-11-201 "home care organization" provides home health services, home medical equipment services or hospice services to patients on an outpatient basis in either their regular or temporary place of residence.

(~~31~~30) Home Health Aide/Hospice Aide. A person who has completed a total of seventy-five (75) hours of training which included sixteen (16) hours of clinical training prior to or during the first three (3) months of employment and who is qualified to provide basic services, including simple procedures as an extension of therapy services, personal care regarding nutritional needs, ambulation and exercise.

(~~32~~31) Hospice Care Clinical Coordinator. A person identified as being responsible for the clinical management of all aspects of a hospice program. The hospice clinical coordinator must have at least one (1) year of supervisory experience in hospice or home health care and be either a licensed physician or a registered nurse.

(~~33~~32) Hospice Patient. An individual who:

(a) Has been diagnosed as terminally ill;

(b) Has been certified in writing by a physician to have an anticipated life expectancy of six (6) months or less; and,

(c) Has voluntarily requested admission to, and been accepted by a licensed hospice.

(~~34~~33) Hospice Services. A coordinated program of care, under the direction of an identifiable hospice administrator, which provides palliative and supportive medical and other services to hospice patients and their families. Hospice services shall be provided twenty-four (24) hours a day, seven (7) days a week.

(Rule 1200-08-15-.01, continued)

(~~35~~34) Incompetent. A patient or resident who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~36~~35) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~37~~36) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(~~38~~37) Involuntary Transfer. The movement of a patient or resident without the consent of the resident, the resident's legal guardian, next of kin or representative, with required notification to the appropriate agencies.

(~~39~~38) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(~~40~~39) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~41~~40) Licensed Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.

(~~42~~41) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~43~~42) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~44~~43) Medical Director. A licensed physician employed by the residential hospice to be responsible for medical care in the facility.

(~~45~~44) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's or resident's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part.

(~~46~~45) Medical Record. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, and other written electronics, or graphic data prepared, kept, made or maintained in an agency that pertains to confinement or services rendered to patients and residents.

(~~47~~46) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or resident or other medical or surgical treatments to achieve the expressed goals of the informed patient or resident. In the case of the incompetent patient or resident, the patient's or resident's representative expresses the goals of the patient or resident.

(~~48~~47) Medical Social Services. When provided, shall be given by a certified master social worker, a licensed clinical social worker, or by a social worker or social work assistant employed by the residential hospice and under the supervision of a certified master social worker or licensed clinical social worker, and in accordance with the plan of care. The medical social services provider shall assist the physician and other team members in understanding the significant social and emotional factors related to the health problems, participate in the development of the plan of care, prepare clinical and progress notes, work

(Rule 1200-08-15-.01, continued)

with the family, utilize appropriate community resources, participate in discharge planning and in-service programs, and act as a consultant to other organization personnel.

(~~49~~48) N.F.P.A. The National Fire Protection Association.

(~~50~~49) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~51~~50) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~52~~51) Palliative. The reduction or abatement of pain or troubling symptoms by appropriate coordination of all elements of the hospice care team to achieve needed relief of distress.

(~~53~~52) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(~~54~~53) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~55~~54) Personally Informing. A communication by any effective means from the patient or resident directly to a health care provider.

(~~56~~55) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

(~~57~~56) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~58~~57) Physical Therapist Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(~~59~~58) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~60~~59) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.

(~~61~~60) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.

(~~62~~61) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's or resident's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~63~~62) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(Rule 1200-08-15-.01, continued)

(~~64~~63) Residential Hospice. A licensed homelike residential facility designed, staffed and organized to provide hospice and/or HIV care services, except such services shall be provided at such residential facility rather than the patient's or resident's regular or temporary place of residence. A residential hospice shall not provide hospice and/or HIV care services to any person other than a hospice and/or HIV resident.

(~~65~~64) Respiratory Therapist. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~66~~65) Respiratory Therapy Technician. A person currently licensed as such by the Tennessee Board of Respiratory Care.

(~~67~~66) Respite Care. A short-term period of inpatient care provided to a hospice patient only when necessary to relieve the family members or other persons caring for the patient.

(~~68~~67) Secured Unit. A facility or distinct part of a facility where the residents are intentionally denied egress by any means.

(~~69~~68) Shall or Must. Compliance is mandatory.

(~~70~~69) Social Worker. An individual who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education and has one (1) year of social work experience in a health care setting.

(~~71~~70) Social Work Assistant. A person who has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has at least one (1) year of social work experience in a health care setting. Social work related fields include bachelor/masters degrees in psychology, sociology, human services (behavioral sciences, not human resources), masters degree in counseling fields (psychological guidance and guidance counseling) and degrees in gerontology.

(~~72~~71) Speech Language Pathologist. A person currently licensed as such by The Tennessee Board of Communication Disorders and Sciences.

(~~73~~72) Spiritual Counselor. A person who has met the requirements of a religious organization to serve the constituency of that organization.

(~~74~~73) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(~~75~~74) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(~~76~~75) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(~~77~~76) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these regulations.

(Rule 1200-08-15-.01, continued)

(~~78~~77) Surrogate. An individual, other than a patient's or resident's agent or guardian, authorized to make a health care decision for the patient or resident.

(~~79~~78) Terminally ill. An individual with a medical prognosis that his or her life expectancy is six (6) months or less if the illness runs its normal course.

(~~80~~79) Transfer. The movement of a patient or resident at the direction of a physician or other qualified medical personnel when a physician is not readily available, but does not include such movement of a patient or resident who leaves the facility against medical advice.

(~~81~~80) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient or resident.

~~(82) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.~~

(81) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(83) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.~~

~~(84) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

(~~85~~82) Volunteer. An individual who agrees to provide services to a hospice care patient or HIV resident and/or family member(s), without monetary compensation, with appropriate supervision by the facility.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed November 22, 2005; effective February 5, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-15-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate, or maintain in the State of Tennessee any residential hospice without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic area specified by the certificate of need or at the time of the original licensing. The name of the residential hospice shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the residential hospice.

(2) In order to make application for a license:

(Rule 1200-08-15-.10, continued)

(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county, and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is in Tennessee, the facility must ensure that it has all necessary state and local approvals, and such approvals shall be available for review. If the off-site location is in another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that shall not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily-cleanable material and shall be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000.*

1200-08-15-.11 RECORDS AND REPORTS.

(1) A yearly statistical report, the "Joint Annual Report" shall be submitted to the department. The forms are mailed to each residential hospice by the department each year. The forms must be completed and returned to the department as requested.

(2) The residential hospice shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Failure to report a communicable disease may result in disciplinary action, including revocation of the facility's license.

~~(3) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.~~

~~(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:~~

~~1. medication errors;~~

~~2. aspiration in a non-intubated patient related to conscious/moderate sedation;~~

~~3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;~~

~~4. volume overload leading to pulmonary edema;~~

(Rule 1200-08-15-.11, continued)

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

7. burns of a second or third degree;

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

(i) procedure related injury requiring repair or removal of an organ;

(ii) hemorrhage;

(iii) displacement, migration or breakage of an implant, device, graft or drain;

(iv) post operative wound infection following clean or clean/contaminated case;

(v) any unexpected operation or reoperation related to the primary procedure;

(vi) hysterectomy in a pregnant woman;

(vii) ruptured uterus;

(viii) circumcision;

(ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(Rule 1200-08-15-.11, continued)

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a

(Rule 1200-08-15-.11, continued)

~~disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.~~

~~(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.~~

~~(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.~~

~~(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.~~

~~(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.~~

~~(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(3) The residential hospice shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(4) The residential hospice shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the residential hospice or to the health and safety of its patients and personnel; and

(Rule 1200-08-15-.11, continued)

(d) Fires at the residential hospice that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

(45) The residential hospice shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file, and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(e) Federal Health Care Financing Administration surveys and inspections, if any;

(f) Orders of the Commissioner or Board, if any;

(g) Comptroller of the Treasury's audit reports and finding, if any; and,

(h) Maintenance records of all safety equipment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, and 68-11-216.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-08-15-.12 PATIENT/RESIDENT RIGHTS.

(1) The residential hospice shall establish and implement written policies and procedures setting forth the rights of patients and residents for the protection and preservation of dignity and individuality. Each patient and resident has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To privacy, for visits by his/her spouse or significant other;

(c) To share a room with his/her spouse or significant other;

(d) To be different in order to promote social, religious, and psychological well being;

(e) To privately talk and/or meet with and see any person;

(f) To send and receive mail promptly and unopened;

(g) To be free from mental and physical abuse. Should this right be violated, the facility must notify the Department within five (5) business days of the incident and the Tennessee Department of Human Services, Adult Protective Services as required by T.C.A. §71-6-101 et seq;

(h) To be free from chemical and physical restraints;

Rule 1200-08-15-.12, continued)

(b) When necessary to protect and preserve the rights of the patients or residents in the facility; or

(c) When contradicted by the explicit provisions of another rule of the board.

(3) Any reduction in patients' or resident's rights must be explicit, reasonable, appropriate to the justification, the least restrictive response feasible, shall be explained to the patient or resident, and must be documented in the individual patient's or resident's record by reciting the limitation's reason and scope.

(4) Patients' and/or residents' pets and other animals utilized for pet therapy programs shall be allowed in the facility. The facility shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.

(5) Each patient or resident has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendments filed November 22, 2005; effective February 5, 2006.*

1200-08-15-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each residential hospice shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient or resident who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients or residents. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient or resident could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient or resident could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient or resident, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient or resident by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient or resident upon the death of the patient or resident. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient or resident lacks capacity, and ceases to be effective upon a determination that the patient or resident has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(Rule 1200-08-15-.13, continued)

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient or resident lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's or resident's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's or resident's best interest. In determining the patient's or resident's best interest, the agent shall consider the patient's or resident's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's or resident's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient or resident having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient or resident having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient or resident who is an adult or emancipated minor if and only if:

(Rule 1200-08-15-.13, continued)

1. the patient or resident has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient or resident who lacks capacity, the patient's or resident's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient or resident is receiving health care.

(d) The patient's or resident's surrogate shall be an adult who has exhibited special care and concern for the patient or resident, who is familiar with the patient's or resident's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's or resident's spouse, unless legally separated;

2. the patient's or resident's adult child;

3. the patient's or resident's parent;

4. the patient's or resident's adult sibling;

5. any other adult relative of the patient or resident; or

6. any other adult who satisfies the requirements of 1200-08-15-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient or resident shall be eligible to serve as the patient's or resident's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or resident or in accordance with the patient's or resident's best interests;

2. The proposed surrogate's regular contact with the patient or resident prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient or resident during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient or resident lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-15-.13(16)(c) thru 1200-08-15-.13(16)(g) is reasonably

(Rule 1200-08-15-.13, continued)

available, the designated physician may make health care decisions for the patient or resident after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's or resident's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's or resident's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's or resident's best interest. In determining the patient's or resident's best interest, the surrogate shall consider the patient's or resident's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient or resident may make all health care decisions for the patient or resident that the patient or resident could make on the patient's or resident's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient or resident upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's or resident's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient or resident is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-15-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's or resident's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient or resident by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient or resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(Rule 1200-08-15-.13, continued)

(a) A guardian shall comply with the patient's or resident's individual instructions and may not revoke the patient's or resident's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient or resident to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient or resident lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's or resident's current clinical record and communicate the determination to the patient or resident, if possible, and to any person then authorized to make health care decisions for the patient or resident.

(19) Except as provided in 1200-08-15-.13(20) thru 1200-08-15-.13(22), a health care provider or institution providing care to a patient or resident shall:

(a) comply with an individual instruction of the patient or resident and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient or resident; and

(b) comply with a health care decision for the patient or resident made by a person then authorized to make health care decisions for the patient or resident to the same extent as if the decision had been made by the patient or resident while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or resident or to a person then authorized to make health care decisions for the patient or resident.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-15-.13(20) thru 1200-08-15-.13(22) shall:

(a) promptly so inform the patient or resident, if possible, and any person then authorized to make health care decisions for the patient or resident;

(b) provide continuing care to the patient or resident until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or resident or person then authorized to make health care decisions for the patient or resident refuses assistance, immediately make all reasonable efforts

(Rule 1200-08-15-.13, continued)

to assist in the transfer of the patient or resident to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient or resident has the same rights as the patient or resident to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient or resident, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient or resident in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person~~

(Rule 1200-08-15-.13, continued)

~~authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient or resident is an adult who is capable of making an informed decision, the patient's or resident's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient or resident is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient or resident be resuscitated by the person authorized to consent on the patient's or resident's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient or resident in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's or resident's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a

(Rule 1200-08-15-.13, continued)

copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient or resident in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed November 22, 2005; effective February 5, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-15-.14 DISASTER PREPAREDNESS.

(1) Emergency Electrical Power.

(a) All residential hospices must have one or more on-site electrical generators, which are capable of providing emergency electrical power to at least all life sustaining equipment and life sustaining resources such as: ventilators; blood banks, biological refrigerators, safety switches for boilers, safety lighting for corridors and stairwells and other essential equipment.

(b) Connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source. All emergency power transfer switches shall be labeled as such. Switches affecting heat, ventilation, and all systems shall be labeled.

(c) The emergency power system shall have a minimum of twenty four (24) hours of either propane, gasoline or diesel fuel. The quantity shall be based on its expected or known connected load consumption during power interruptions. In addition, the residential hospice shall have a written contract with an area fuel distributor which guarantees first priority service for re-fills during power interruptions.

(d) The emergency power system (generator) shall be inspected weekly and exercised and under actual load and operating temperature conditions for at least thirty (30) minutes, once each month including automatic and manual transfer of equipment. The generator shall be exercised by trained facility staff who are familiar with the systems operation. Instructions for the operation of the systems and the manual transfer of emergency power shall be maintained with the facility's disaster preparedness plan and shall be separately identified in the plan. Records shall be maintained for all weekly inspections and monthly tests and be kept on file for a minimum of three (3) years.

(2) Physical Facility and Community Emergency Plans.

RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-24
STANDARDS FOR BIRTHING CENTERS

TABLE OF CONTENTS

1200-08-24-.01 DEFINITIONS.

(1) Adult. An individual who has capacity and is at least 18 years of age.

(2) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

(3) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(4) Birthing Center. Any institution, facility, place or building devoted exclusively or primarily to the provision of routine delivery services and postpartum care for mothers and their newborn infants.

(5) Board. The Tennessee Board for Licensing Health Care Facilities.

(6) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a patient to make health care decisions while having the capacity to do so. A patient shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.

(7) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to restore or support cardiopulmonary functions in a patient, whether by mechanical devices, chest compression, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(8) Certified Nurse Midwife (CNM). A registered nurse currently licensed as such by the Tennessee Board of Nursing and certified by the American College of Nurse-Midwives and qualified to deliver midwifery services.

(Rule 1200-08-24-.01, continued)

(9) Certified Professional Midwife (CPM). A North American Registry of Midwives (NARM) certified midwife, who must have midwifery skills and experience evaluated and pass written and skills examinations.

(10) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(11) Competent. A patient who has capacity.

~~(12) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:~~

~~(a) the action(s) implemented to prevent the reoccurrence of the unusual event,~~

~~(b) the time frames for the action(s) to be implemented,~~

~~(c) the person(s) designated to implement and monitor the action(s), and~~

~~(d) the strategies for the measurements of effectiveness to be established.~~

(~~13~~12) Department. The Tennessee Department of Health.

(~~14~~13) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.

(~~15~~14) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical record which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(~~16~~15) Emancipated Minor. Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.

(~~17~~16) Emergency Responder. A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.

(~~18~~17) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(~~19~~18) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state, or federal regulations.

(~~20~~19) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

(~~21~~20) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(~~22~~21) Health Care Decision-maker. In the case of a patient who lacks capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed guardian or conservator with health care

(Rule 1200-08-24-.01, continued)

decision-making authority, the patient's surrogate as determined pursuant to Rule 1200-08-24-.12 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

(~~23~~22) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(~~24~~23) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

(~~25~~24) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with services of a physician or dentist, of one (1) or more nonrelated persons who may be suffering from deformity. injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment.

(~~26~~25) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(~~27~~26) Individual instruction. An individual's direction concerning a health care decision for the individual.

(~~28~~27) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(~~29~~28) Licensee. The person or body to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(~~30~~29) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(~~31~~30) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations, and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(~~32~~31) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or other medical or surgical treatments to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the patient's representative expresses the goals of the patient.

(~~33~~32) Member of the Professional Medical Community. A professional employed by the birthing center and on the premises at the time of a voluntary delivery.

(~~34~~33) NFPA. The National Fire Protection Association.

(~~35~~34) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(Rule 1200-08-24-.01, continued)

(~~36~~35) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(~~37~~36) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(~~38~~37) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(~~39~~38) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.

(~~40~~39) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.

(~~41~~40) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(~~42~~41) Routine Delivery Services. Services provided by a physician or a certified professional midwife practicing when these rules become final or a certified nurse midwife related to the normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health, promoting a family-centered approach to care and viewing pregnancy and delivery as a normal physiological process requiring limited technological and pharmacological support.

(~~43~~42) Shall or Must. Compliance is mandatory.

(~~44~~43) Stabilize. To provide such medical treatment of the emergency medical condition as may be necessary to assure, within reasonable medical probability, that the condition will not materially deteriorate due to the transfer as determined by a physician or other qualified medical personnel when a physician is not readily available.

(~~45~~44) State.A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(~~46~~45) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(~~47~~46) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(~~48~~47) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(~~49~~48) Transfer. The movement of a patient to a hospital at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

(Rule 1200-08-24-.01, continued)

(~~50~~49) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

~~(51) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.~~

(50) Universal Do Not Resuscitate Order. A written order that applies regardless of treatment setting and that is signed by the patient's physician which states that in the event a patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(52) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.~~

~~(53) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

(~~54~~51) Voluntary Delivery. The action of a mother in leaving an unharmed infant aged seventy-two (72) hours or younger on the premises of a birthing center with any birthing center employee or member of the professional medical community without expressing any intention to return for such infant, and failing to visit or seek contact with such infant for a period of thirty (30) days thereafter.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255 and 68-11-1802.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed September 17, 2002; effective December 1, 2002. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed January 3, 2006; effective March 19, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-24-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or any state, county or local government unit, or any division, department, board or agency thereof shall establish, conduct, operate, or maintain in the State of Tennessee any birthing center without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the facility.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars ($1,080.00). The fee must be submitted with the application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the birthing center until a license has been issued. Applicants shall not hold themselves out to the public as being a birthing center until the license

(Rule 1200-08-24-.09, continued)

that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this rule. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.

(11) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily-cleanable material, and shall be kept on elevated platforms.

Authority: *T.C.A. §§ 4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*

1200-08-24-.10 RECORDS AND REPORTS.

(1) A report of all births, deaths and stillbirths which have occurred in the birthing center shall be filed with the local registrar in the county where the institution is located. The report shall be filed on the third (3rd) working day of each month on a form furnished by the State Registrar. The report shall state whether or not the list is complete for all events which have occurred in the facility during the preceding calendar month, and if not complete, shall show the number of events not included in the report. If no birth, death, or stillbirth occurred in the facility, the words "No Report" shall be entered on the form and forwarded to the local registrar.

(2) The Joint Annual Report, a calendar year statistical report, shall be filed with the department's Bureau of Information Resources no later than sixty (60) days following the twelve (12) months ending December 31.

(3) The birthing center shall report each case of communicable disease to the local county health officer in the mariner provided by existing regulations of the department. Repeated failure to report communicable diseases shall be cause for revocation of a facility license.

~~(4) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.~~

~~(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:~~

~~1. medication errors;~~

~~2. aspiration in a non-intubated patient related to conscious/moderate sedation;~~

~~3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;~~

~~4. volume overload leading to pulmonary edema;~~

(Rule 1200-08-24-.10, continued)

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

7. burns of a second or third degree;

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

(i) procedure related injury requiring repair or removal of an organ;

(ii) hemorrhage;

(iii) displacement, migration or breakage of an implant, device, graft or drain;

(iv) post operative wound infection following clean or clean/contaminated case;

(v) any unexpected operation or reoperation related to the primary procedure;

(vi) hysterectomy in a pregnant woman;

(vii) ruptured uterus;

(viii) circumcision;

(ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(Rule 1200-08-24-.10, continued)

~~(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;~~

~~(xxi) restraint related incidents; or~~

~~(xxii) poisoning occurring within the facility.~~

~~(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:~~

~~1. strike by the staff at the facility;~~

~~2. external disaster impacting the facility;~~

~~3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and~~

~~4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.~~

~~(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.~~

~~(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.~~

~~(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.~~

~~(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The~~

(Rule 1200-08-24-.10, continued)

~~report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.~~

~~(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.~~

~~(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.~~

~~(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.~~

~~(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.~~

~~(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(4) The birthing center shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(5) The birthing center shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the birthing center or to the health and safety of its patients and personnel; and

(Rule 1200-08-24-.10, continued)

(d) Fires at the birthing center that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

(~~5~~6) The birthing center shall report information contained in the medical records of patients who have cancer or precancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(~~6~~7) The birthing center shall retain legible copies of the records and reports specified in this paragraph for the thirty-six (36) month period following their issuance. Copies of these reports shall be maintained in a single file at a location convenient to the public and, during normal business hours, they shall be promptly produced for the inspection of any person who requests to view them. Each patient and each person assuming any financial responsibility for a patient must be fully informed, before or at the time of admission, of the availability of these reports to the public, of their location within the facility, and given an opportunity to inspect the file before entering into any monetary agreement with the facility.

(a) Local fire safety inspections.

(b) Local building code inspections, if any.

(c) Fire marshal reports.

(d) Department licensure and fire safety inspections and surveys.

(e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any.

(f) Federal Health Care Financing Administration surveys and inspections, if any.

(g) Orders of the Commissioner or Board, if any.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-08-24-.11 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the department and the Tennessee Department of Human Services, Adult Protective Services;

(c) To refuse treatment. The patient must be informed of the consequences of that decision, the refusal and its reason must be reported to the physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in his or her medical record; and

(Rule 1200-08-24-.11, continued)

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The birthing center must have policies to govern access and duplication of the patient's record.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment, including resuscitative services. This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed January 3, 2006; effective March 19, 2006.*

1200-08-24-.12 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(1) Pursuant to this Rule, each birthing center shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

~~(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.~~

(5) A facility may use any advanced directive form that meets the requirements of the Tennessee Health Care Decisions Act or has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent

(Rule 1200-08-24-.12, continued)

shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(Rule 1200-08-24-.12, continued)

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-08-24-.12(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-08-24-.12(16)(c) thru 1200-08-24-.12(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(Rule 1200-08-24-.12, continued)

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-08-24-.12(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in

(Rule 1200-08-24-.12, continued)

the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-08-24-.12(20) thru 1200-08-24-.12(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-08-24-.12(20) thru 1200-08-24-.12(22) shall:

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(Rule 1200-08-24-.12, continued)

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

~~(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:~~

~~1. with the consent of the patient; or~~

~~2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or~~

~~3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.~~

(a) The Physicians Order for Scope of Treatment (POST) form, a form meeting the provisions of the Health Care Decisions Act and approved by the Board for Licensing Health Care Facilities, may be used as the Universal Do Not Resuscitate Order by all facilities. A Universal Do Not Resuscitate Order may be used by a physician for a patient whom the physician has a physician/patient relationship, but only:

1. with the consent of the patient; or

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of

(Rule 1200-08-24-.12, continued)

the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

~~(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.~~

(e) When a person with a Universal Do Not Resuscitate Order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the Universal Do Not Resuscitate Order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the Universal Do Not Resuscitate Order accompanies the individual in transport to the receiving health care facility. Upon admission, the receiving facility shall make the Universal Do Not Resuscitate Order a part of the individual's record. The POST form promulgated by the Board for Licensing Health Care Facilities shall serve as the Universal Do Not Resuscitate Order form when transferring an individual from one health care facility to another health care facility.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

(Rule 1200-08-24-.12, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815 .* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed January 3, 2006; effective March 19, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-08-24-.13 DISASTER PREPAREDNESS.

(1) Physical Facility and Community Emergency Plans.

(a) Every birthing center shall have a current internal emergency plan, or plans, that provides for fires, bomb threats, severe weather, utility service failures, plus any local high risk situations such as floods, earthquakes, toxic fumes and chemical spills.

(b) The plan(s) must include provisions for the relocation of persons within the building and/or either partial or full building evacuation. Plans that provide for the relocation of patients to other healthcare facilities must have written agreements for emergency transfers. Their agreements may be mutual, i.e., providing for transfer either way.

(c) Copies of the plan(s), either complete or outlines, shall be available to all staff. Provisions that have security implications may be omitted from the outline versions. Familiarization information shall be included in employee orientation sessions and more detailed instructions must be included in continuing education programs. Records of orientation and education programs must be maintained for at least three (3) years.

(d) Drills of the fire safety plan shall be conducted at least once a year on each major work shift, for a minimum of three times a year for each facility. A combined drill of the other internal emergency plans shall be conducted at least once a year. The risk focus may vary by drill. Both types of drills are for the purposes of educating staff, resource determination, testing personal safety provisions and communications with other facilities and community agencies. Records which document and evaluate these drills must be maintained for at least three (3) years.

(e) As soon as possible, real situations that result in a response by local authorities must be documented. This includes a critique of the activation of the plan. Actual documented situations that provided educational and training value may be substituted for a drill.

(2) Emergency Planning with Local Government Authorities.

(a) All birthing centers shall establish and maintain communications with the local office of the Tennessee Emergency Management Agency. This includes the provision of the information and procedures that are needed for the local comprehensive emergency plan. The facility shall cooperate, to the extent possible, in area disaster drills and local emergency situations.

(b) A file of documents demonstrating communications and cooperation with the local agency must be maintained.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998.*

1200-08-24-.14 APPENDIX I

(1) Physician Orders for Scope of Treatment (POST) Form

RULES
OF
TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-25
STANDARDS FOR ASSISTED-CARE LIVING FACILITIES

TABLE OF CONTENTS

1200-08-25-.01 PURPOSE.

(1) The purpose of assisted-care living services is to:

(a) Promote the availability of appropriate residential facilities for the elderly and adults with disabilities in the least restrictive and most homelike environment;

(b) Provide assisted-care living services to residents in facilities by meeting each individual's medical and other needs safely and effectively; and

(c) Enhance the individual's ability to age in place while promoting personal individuality, respect, independence, and privacy.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed November 25, 1998; effective February 8, 1999. Amendment filed September 13, 2002; effective November 27, 2002. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed January 24, 2006; effective April 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009.*

1200-08-25-.02 DEFINITIONS.

(1) "Activities of Daily Living (ADL's)" means those activities which indicate an individual's independence in eating, dressing, personal hygiene, bathing, toileting, ambulating, and medication management.

(2) "Administering medication" means the direct application of a single dose of a medication to the body of a resident by injection, inhalation, ingestion, topical application or by any other means.

(3) "Administrator" means a natural person designated by the licensee to have the authority and responsibility to manage the ACLF and who is appropriately certified as an assisted-care living facility administrator or is currently licensed in Tennessee as a nursing home administrator as required by T.C.A. §§ 63-16-101, et seq.

(4) "Adult" means a person 18 years of age or older.

(5) "Ambulatory" means the resident's ability to bear weight, pivot and safely walk with the use of a cane, walker, or other mechanical supportive device with or without the minimal assistance of another person. The resident must be physically and mentally capable of self-preservation by evacuating in response to an emergency. A resident who requires a wheelchair must be capable of transferring to and propelling the wheelchair independently.

(6) "Assisted-care living facility (ACLF)" means a building, establishment, complex or distinct part thereof that accepts primarily aged persons for domiciliary care and services.

(7) "Assisted-care living facility resident" or "resident" means primarily an aged person who requires domiciliary care, and who upon admission to the facility, if not ambulatory, is capable of self-transfer from the bed to a wheelchair or similar device and is capable of propelling such wheelchair or similar device independently. Such a resident may require one or more of the following services: room and board, assistance with non-medical activities of daily living, administration of typically self-administered medications, and medical services subject to the limitations of these rules.

(8) "Assessment" means a procedure for determining the nature and extent of the problem(s) and needs of a resident or potential resident to ascertain if the ACLF can adequately address those problems, meet those needs, and secure information for the use in the development of the individual care plan.

(9) "Cardiopulmonary resuscitation (CPR)" means the administering of any means or device to restore or support cardiopulmonary functions in a resident, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirators, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(10) "Continuous nursing care" means round-the-clock observation, assessment, monitoring, supervision, or provision of nursing services that can only be performed by a licensed nurse.

(11) "Distinct part" means a unit or part thereof that is organized and operated to give a distinct type of care within the larger organization which renders other types or levels of care. "Distinct" denotes both organizational and physical separateness. A distinct part of an ACLF must be physically identifiable and be operated distinguishably from the rest of the institution. It must consist of all the beds within that unit such as a separate building, floor, wing or ward. Several rooms at one end of a hall or one side of a corridor is acceptable as a distinct part of an ACLF.

(12) "Do Not Resuscitate (DNR) Order" means a written order entered by the resident's treating physician in the resident's medical record which states that in the event the resident suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(13) "Emergency" means any situation or condition which presents an imminent danger of death or serious physical or mental harm to residents.

(14) "Health care" means any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

(15) "Health care decision" means an individual's consent, refusal of consent or withdrawal of consent to health care.

(16) "Health care decision-maker" means that in the case of a resident who lacks capacity, the resident's health care decision-maker is one of the following: the resident's health care agent as specified in an advance directive, the resident's court-appointed guardian or conservator with health care decision-making authority, the resident's surrogate as determined pursuant T.C.A. § 68-11-1806, or the individual's designated physician pursuant to T.C.A. § 68-11-1802(a)(4).

(17) "Infectious waste" means solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure could result in an infectious disease.

(18) "Licensed health care professional" means any health care professional currently licensed by the State of Tennessee to practice within the scope of a regulated profession, such as a nurse practitioner, registered nurse, licensed practical nurse, (nurses may be licensed or hold multistate licensure pursuant to Tennessee Code Annotated §§ 63-7-101 et seq.), dietitian, dentist, occupational therapist, pharmacist, physical therapist, physician, physician assistant, psychologist, clinical social worker, speech-language pathologist, and emergency service personnel.

(19) "Licensee" means the person, association, partnership, corporation, company or public agency to which the license is issued.

(20) "Life threatening or serious injury" means an injury requiring the resident to undergo significant diagnostic or treatment measures.

(21) "Medical record" means documentation of medical histories, nursing and treatment records, care needs summaries, physician orders, and records of treatment and medication ordered and given which must be maintained by the ACLF, regardless of whether such services are rendered by ACLF staff or by arrangement with an outside source.

(22) "Medically inappropriate treatment" means resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the resident or other medical or surgical treatments that cannot be expected to achieve the expressed goals of the informed resident.

(23) "NFPA" means the National Fire Protection Association.

(24) "Patient abuse" means patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(25) "Person" means an individual, association, estate, trust, corporation, partnership, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(26) "Personal services" means those services rendered to residents who need supervision or assistance in activities of daily living. Personal services do not include nursing or medical care.

(Rule 1200-08-25-.02, continued)

(27) "Power of Attorney for Health Care" means the legal designation of an agent to make health care decisions for the individual granting such power under T.C.A. Title 34, Chapter 6, Part 2.

(28) "Primarily aged" means that a minimum of fifty-one percent (51%) of the population of the facility is at least sixty- two (62) years of age.

(29) "Resident sleeping unit" means a single unit providing sleeping facilities for one or more persons. Resident sleeping units can also include permanent provisions for living, eating and sanitation.

(30) "Responsible attendant" means the individual person designated by the licensee to provide personal services to the residents.

(31) "Secured unit" means a distinct part of an ACLF where the residents are intentionally denied egress by any means.

(32) "Self-administration of medication" means assistance in reading labels, opening dosage packaging, reminding residents of their medication, or observing the resident while taking medication in accordance with the plan of care.

(33) "Supervising health care provider" means the health care provider who has undertaken primary responsibility for an individual's health care.

(34) "Surrogate" means an individual, other than a resident's agent or guardian, authorized to make a health care decision for the resident pursuant to T.C.A. § 68-11-1806.

(35) "Treating health care provider" means a health care provider directly or indirectly involved in providing health care to a resident at the time such care is needed by the resident.

(36) "Universal Do Not Resuscitate Order" means a written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted.

~~(37) "Unusual event" means an unexpected occurrence or accident that is unrelated to the natural course of the resident's illness or underlying condition that results in death, life threatening or serious injury to a resident. An unusual event also includes an incident resulting in the abuse of a resident.~~

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-210.* ***Administrative History:*** *Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Amendment filed February 23, 2007; effective May 9, 2007. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009.*

1200-08-25-.03 LICENSING REQUIREMENTS.

(1) An applicant for an ACLF license shall submit the following to the office of the Board for Licensing Health Care Facilities:

(a) A completed application on a form approved by the Board;

(b) Nonrefundable application fee;

(Rule 1200-08-25-.12, continued)

(e) Maintenance records of all safety equipment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed January 24, 2006; effective April 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009.*

1200-08-25-.13 REPORTS.

~~(1) Unusual events shall be reported to the Department of Health by the ACLF in accordance with T.C.A. §§ 68-11-211, et seq.~~

(1) The ACLF shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(2) The ACLF shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(c) Disruption of any service vital to the continued safe operation of the ACLF or to the health and safety of its patients and personnel; and

(d) Fires at the ACLF that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

(~~2~~3) An ACLF shall file the Joint Annual Report of Assisted Care Living Facilities with the department. The forms shall be furnished and mailed to each ACLF by the department each year and the forms must be completed and returned to the department as required.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-211.* ***Administrative History:*** *Original rule filed February 9, 1998; effective April 25, 1998. Public necessity rule filed May 13, 2009; effective through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009.*

1200-08-25-.14 RESIDENT RIGHTS.

(1) An ACLF shall ensure at least the following rights for each resident:

(a) To be afforded privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the ACLF shall notify the department and the Tennessee Department of Human Services, Adult Protective Services at 1-888-277-8366;

(c) To refuse treatment. An ACLF must inform the resident of the consequences of that decision. The ACLF must report the resident's refusal and its reason to the resident's treating physician and it must document such in the resident's record;